

General

Title

End stage renal disease (ESRD): percentage of all patient months for adult patients (≥ 18 years old) whose delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was $\text{spKt/V} \geq 1.2$.

Source(s)

Centers for Medicare & Medicaid Services (CMS). Measure information form: delivered dose of hemodialysis above minimum. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 6 p.

Centers for Medicare & Medicaid Services (CMS). Measure justification form: delivered dose of hemodialysis above minimum. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 21 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Outcome

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of all patient months for adult patients (greater than or equal to 18 years old) whose delivered dose of hemodialysis (calculated from the last measurement of the month using the urea kinetic modeling (UKM) or Daugirdas II formula) was spKt/V greater than or equal to 1.2.

Rationale

Published studies indicate there is an association between low spKt/V and increased mortality.

Furthermore, the 2006 Kidney Disease Outcomes Quality Initiative (KDOQI) Hemodialysis Adequacy Guidelines indicate "minimally adequate dose of hemodialysis given 3 times per week to patients with K_r less than 2 mL/min/1.73 m² should be an spKt/V of 1.2 per dialysis" (National Kidney Foundation, 2006).

In considering target spKt/V, the pediatric population should receive at least an spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children.

Evidence for Rationale

Centers for Medicare & Medicaid Services (CMS). Measure justification form: delivered dose of hemodialysis above minimum. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 21 p.

National Kidney Foundation. KDOQI clinical practice guidelines and clinical practice recommendations for 2006 updates: hemodialysis adequacy. New York (NY): National Kidney Foundation; 2006. various p.

Primary Health Components

End stage renal disease (ERSD); hemodialysis; spKt/V dose

Denominator Description

To be included in the denominator for a particular month, the patient must be on hemodialysis for the entire month, be greater than or equal to 18 years old at the beginning of the month, must have had end stage renal disease (ESRD) for greater than 90 days at the beginning of the month, must be dialyzing thrice weekly during the month, and must be assigned to that facility for the entire month.

See the related "Denominator Inclusions/Exclusions" field.

Numerator Description

Number of patient months in denominator in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the urea kinetic modeling [UKM] or Daugirdas II formula) was a spKt/V greater than or equal to 1.2 (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

High Priority

The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult population, outcome studies have shown an association between dose of hemodialysis in terms of small solute removal and clinical outcomes (Lowrie et al., 1981; Owen et al., 1993). In addition, at least one prior study demonstrates that a change in dialysis dose is associated with a change in patient outcome (Wolfe et al., 2005). Furthermore, studies demonstrate an association between dialysis adequacy as measured by Kt/V and outcomes (Wolfe et al., 2000; Port et al., 2002; Port et al., 2004).

Since endorsement of this measure, published literature suggests there is insufficient evidence that compares methods of dialysis adequacy measurement, particularly measures that demonstrate superiority of alternative measures over spKt/V. It should also be noted that there have been no changes in the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Methods for Measuring and Expressing Hemodialysis Dose (CPG 2). Indeed, as stated in the KDOQI 2006 update, "The delivered Kt/V determined by single-pool urea kinetic modeling continues to be preferred as the most precise and accurate measure of dialysis" (National Kidney Foundation, 2006).

Currently, frequent hemodialysis (more than thrice weekly) is still rare, with approximately 1% of dialysis patients receiving this modality. As this population grows and the evidence base for alternative adequacy measurement methods grows, the use of standard Kt/V (stdKt/V), in particular should be evaluated by a Clinical Technical Expert Panel (CTEP), including a target measure because of the potential for a growing percentage of patients being dialyzed more than thrice weekly and where spKt/V is not comparable across treatment schedules.

Additional considerations for future expert review of the use of spKt/V measure relates to women and smaller patients. Recent studies that examine dialysis dosing in women and smaller patients should be considered (Daugirdas et al., "Can rescaling," 2010; Daugirdas et al., "Dose of dialysis," 2010). In addition, because prior studies that evaluate the impact of hemodialysis dose on mortality have used spKt/V as the measure of hemodialysis adequacy, alternative methods of adequacy measurement should also be considered. Finally, recent clinical studies suggest the benefit of using online measurement methods for assessing ionic clearance, and these tools should be considered in the future (Lowrie et al., 2006).

Evidence for Additional Information Supporting Need for the Measure

Centers for Medicare & Medicaid Services (CMS). Measure justification form: delivered dose of hemodialysis above minimum. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 21 p.

Daugirdas JT, Greene T, Chertow GM, Depner TA. Can rescaling dose of dialysis to body surface area in the HEMO study explain the different responses to dose in women versus men?. Clin J Am Soc Nephrol. 2010 Sep;5(9):1628-36. [PubMed](#)

Daugirdas JT, Hanna MG, Becker-Cohen R, Langman CB. Dose of dialysis based on body surface area is markedly less in younger children than in older adolescents. Clin J Am Soc Nephrol. 2010 May;5(5):821-7. [PubMed](#)

Lowrie EG, Laird NM, Parker TF, Sargent JA. Effect of the hemodialysis prescription of patient morbidity: report from the National Cooperative Dialysis Study. N Engl J Med. 1981 Nov 12;305(20):1176-81. [PubMed](#)

Lowrie EG, Li Z, Ofsthun NJ, Lazarus JM. Dose of dialysis based on body surface area is markedly less in younger children than in older adolescents. Kidney Int. 2006 Jul;70(1):211-7. [PubMed](#)

National Kidney Foundation. KDOQI clinical practice guidelines and clinical practice recommendations

for 2006 updates: hemodialysis adequacy. New York (NY): National Kidney Foundation; 2006. various p.

Owen WF, Lew NL, Liu Y, Lowrie EG, Lazarus JM. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. *N Engl J Med*. 1993 Sep 30;329(14):1001-6. [25 references] [PubMed](#)

Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA. Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. *J Am Soc Nephrol*. 2002 Apr;13(4):1061-6. [31 references] [PubMed](#)

Port FK, Wolfe RA, Hulbert-Shearon TE, McCullough KP, Ashby VB, Held PJ. High dialysis dose is associated with lower mortality among women but not among men. *Am J Kidney Dis*. 2004 Jun;43(6):1014-23. [PubMed](#)

Wolfe RA, Ashby VB, Daugirdas JT, Agodoa LY, Jones CA, Port FK. Body size, dose of hemodialysis, and mortality. *Am J Kidney Dis*. 2000 Jan;35(1):80-8. [PubMed](#)

Wolfe RA, Hulbert-Shearon TE, Ashby VB, Mahadevan S, Port FK. Improvements in dialysis patient mortality are associated with improvements in urea reduction ratio and hematocrit, 1999 to 2002. *Am J Kidney Dis*. 2005 Jan;45(1):127-35. [PubMed](#)

Extent of Measure Testing

Reliability Testing

Method of Reliability Testing

The developer used January 2013 – December 2013 CROWNWeb and Medicare Claims data to calculate the inter-unit reliability (IUR) for the overall 12 months to assess the reliability of this measure. The National Quality Forum (NQF)-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The IUR measures the proportion of the measure variability that is attributable to the between-facility variance. The yearly based IUR was estimated using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. The developer notes that the method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. Since this measure is not normally distributed, the IUR value should be interpreted with some caution.

Statistical Results from Reliability Testing

For reliability the developer calculated the monthly and annual IUR across the 12 reporting months. As explained above, the method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. The IUR is 0.942, which is high and suggests 94% of variation in the measure is attributed to between facility variation and approximately 6% attributed to within facility variation. The 95% confidence interval is (0.940, 0.944).

Interpretation

The IUR suggest this measure is reliable. However, since the distribution of performance scores is skewed, the IUR value should be interpreted with some caution.

Validity Testing

Method of Validity Testing

Validity was assessed using Spearman correlations to measure the association between facility level performance scores and the 2013 standardized mortality ratio (SMR) (NQF 0369) and standardized hospitalization ratio (SHR) (NQF 1463).

This measure is also established on the basis of face validity. The measure has been reviewed and approved by clinical technical expert panels (TEPs). The individual measures are also NQF endorsed. Achieving target Kt/V is included in the End-stage Renal Disease (ESRD) Quality Incentive Program (QIP) beginning with program year (PY) 2015, and has been reported on Dialysis Facility Compare (DFC) since January 2013.

Statistical Results from Validity Testing

The spearman correlation between the HD Kt/V measure and SMR is -0.085, and statistically significant (p less than .0001).

The spearman correlation between HD Kt/V measure and SHR is -0.160, statistically significant (p less than .0001).

Interpretation

The Spearman correlation coefficients indicate higher facility level percentages of patients that achieve the Kt/V target is associated lower standardized mortality and hospitalization, respectively, although the magnitude of the association is low.

Refer to the original measure documentation for additional information.

Evidence for Extent of Measure Testing

Centers for Medicare & Medicaid Services (CMS). Measure justification form: delivered dose of hemodialysis above minimum. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 21 p.

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory Procedure/Imaging Center

Hospital Outpatient

Managed Care Plans

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Single Health Care Delivery or Public Health Organizations

Statement of Acceptable Minimum Sample Size

Does not apply to this measure

Target Population Age

Age greater than or equal to 18 years

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Data Collection for the Measure

Case Finding Period

The measurement period

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Clinical Condition

Patient/Individual (Consumer) Characteristic

Therapeutic Intervention

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions

To be included in the denominator for a particular month, the patient must be on hemodialysis (HD) for the entire month, be greater than or equal to 18 years old at the beginning of the month, must have had end stage renal disease (ESRD) for greater than 90 days at the beginning of the month, must be dialyzing thrice weekly during the month, and must be assigned to that facility for the entire month.

Note:

Patients with missing Kt/V values are not excluded from the measure. Therefore, patients for whom a Kt/V value is missing for the month are still included in the denominator. This is designed to ensure that facilities will still be evaluated for the measure. Refer to the original measure documentation for additional denominator details and calculation algorithm/measure logic.

Exclusions

Exclusions that are implicit in the denominator definition include:

- Peritoneal dialysis patients
- Pediatric patients (less than 18 years old)
- Those patients not on thrice weekly dialysis
- All patients who have had ESRD for less than 91 days
- Patients not assigned to the facility for the entire month

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions

Number of patient months in denominator in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the urea kinetic modeling [UKM] or Daugirdas II formula) was spKt/V greater than or equal to 1.2

Note:

Months with spKt/V greater than or equal to 1.2 are counted in the numerator. Eligible spKt/V values are those greater than or equal to 1.2 during the reporting month. The last spKt/V value reported, not including missing, expired, and not performed, is selected when multiple values are reported in the month. Missing, expired, and not performed will not be counted as achieving the minimum spKt/V threshold.

Exclusions

Unspecified

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Registry data

Type of Health State

Physiologic Health State (Intermediate Outcome)

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Delivered dose of hemodialysis above minimum.

Measure Collection Name

End Stage Renal Disease (ESRD) Quality Measures

Submitter

Centers for Medicare & Medicaid Services - Federal Government Agency [U.S.]

Developer

Centers for Medicare & Medicaid Services - Federal Government Agency [U.S.]

Funding Source(s)

Centers for Medicare & Medicaid Services (CMS)

Composition of the Group that Developed the Measure

The University of Michigan Kidney and Epidemiology Cost Center (UM-KECC), develops, maintains, and updates the End Stage Renal Disease (ESRD) Quality Measures for the Centers for Medicare and Medicaid Services (CMS), under the Quality Measure Development and Maintenance contract with CMS. In addition, UM-KECC works with CMS's Measures Management System (MMS) in the development, evaluation, and reporting of the current ESRD Quality Measures.

Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

Endorser

National Quality Forum - None

NQF Number

not defined yet

Date of Endorsement

2015 Oct 2

Measure Initiative(s)

Dialysis Facility Compare (DFC)

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2015 Sep

Measure Maintenance

Annually

Date of Next Anticipated Revision

Unspecified

Measure Status

Please note: This measure has been updated. The National Quality Measures Clearinghouse is working to update this summary.

Measure Availability

Source available from the [Dialysis Data Web site](#) .

For more information, refer to the [Dialysis Data Web site](#) or contact Casey Parrotte at the Kidney Epidemiology and Cost Center, The University of Michigan, 1415 Washington Heights, Suite 3645 SPHI, Ann Arbor, MI 48109-2029; Phone: 734-763-6611; Fax: 734-763-4004; Email: parrotte@med.umich.edu.

NQMC Status

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Production

Source(s)

Centers for Medicare & Medicaid Services (CMS). Measure information form: delivered dose of hemodialysis above minimum. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015

Centers for Medicare & Medicaid Services (CMS). Measure justification form: delivered dose of hemodialysis above minimum. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 21 p.

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